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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,088	01/18/2002	Graham John Hamilton Melrose	2354/141 (FF34527/02)	6479
7590 Michael L. Goldman NIXON PEABODY LLP Clinton Square P.O. Box 31051 Rochester, NY 14603				
			EXAMINER KHAN, AMINA S	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 12/19/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/053,088

Applicant(s)

MELROSE ET AL.

Examiner

AMINA KHAN

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/15/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7.9-13, 15-17, 25-39, 42, 46, 47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7.9-13, 15-17, 25-39, 42, 46, 47 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to applicant's amendments filed on September 15, 2008.
2. Claims 7,9-13,15-17,25-39,42,46,47 and 49 are pending. Claims 1-6,8,14,18-24,40,41,43-45 and 48 have been cancelled. Claims 7,9 and 49 have been amended.
3. All previous rejections are withdrawn in view of applicant's amendments.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 7,9-13,15-17,25-28,30-39,42,46,47 and 49 are rejected under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 96/38186) in view of Melrose (WO 00/03723).

Melrose '186 et al. teach a method for the treatment of gastrointestinal disease and/or cancer via the ingestion of polymeric compositions in animals or birds in need of said treatment and chemotherapeutic treatments. Melrose teaches the treatment of cancer, the treatment and/or prevention of gastrointestinal disease and/or infection and/or diarrhea comprising administering to said animals or birds an effective amount of a pharmaceutical or veterinary composition or feed additive, comprising an effective amount of a polymer and/or copolymer, having the repeating polymeric unit (I) wherein R is H or alkyl, usually C.sub.1 to C.sub.4, or this unit in hydrated, hemiacetal or acetal form, together with a pharmaceutically or veterinarily acceptable carrier, diluent, adjuvant, excipient and/or controlled release system. See abstract.

Melrose '186 et al. teach a method for the preparation of compositions of poly(2-propenal, 2-propenoic acid) with 0.1-5 moles of carboxyl groups/kg (page 3, lines 25-30). Melrose et al. teach a method of producing pellets or like solid composition, the pellets comprising polymers and/or copolymers as defined in the first embodiment of the invention, mainly within a polymeric matrix, said method as defined in the fourth embodiment of the invention and comprising the steps of: (i) dissolving said polymers and/or copolymers in an aqueous alkaline or basic solution; (ii) neutralizing said solution with acid; (iii) adding to said neutralized solution insoluble, cross-linked, absorbent polymers of acrylic acid and/or copolymers of acrylamide and acrylic acid, to form wet

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swollen pellets; and (iv) optionally, wholly or partially drying said wet swollen pellets. The so-formed wet, swollen pellets may be used either wet, partially dried or wholly dried, as an additive to, for example, animal feed. This system is further designed so that the carboxyl-containing groups of the outer polymeric matrix cause the Subject Polymers to remain essentially contained within the matrix when in the acidic environment of the stomach. However, in the alkaline environment of the duodenum, the carboxyl groups of the matrix become ionized and mutually-repelling, and the pellet rapidly swells to allow the Subject Polymers, aided by repulsion among their own ionic groups, to be excluded by a diffusion process, approximately matching the speed of passage of feed through the duodenum. See page 7, lines 15-35.

Melrose '186 et al. teach that the antimicrobial composition comprises pharmaceutically or veterinarily acceptable binders, sweeteners, disintegrating agents, diluents, flavorings, coating agents, preservatives, lubricants and/or time delay agents. Suitable binders include gum acacia, gelatin, corn starch, gum tragacanth, sodium alginate, carboxymethylcellulose or polyethylene glycol. Suitable flavoring agents include peppermint oil, oil of wintergreen, cherry, orange or raspberry flavoring. Suitable coating agents include polymers or copolymers of acrylic acid and/or methacrylic acid and/or their esters, and/or their amides, waxes, fatty alcohols, zein, shellac or gluten. Melrose teach that liquid forms for oral administration may contain, in addition to the above agents, a liquid carrier. Suitable liquid carriers include water, oils such as olive oil, peanut oil, sesame oil, sunflower oil, safflower oil, arachis oil, coconut oil, liquid paraffin, ethylene glycol, propylene glycol, polyethylene glycol, ethanol, propanol,

isopropanol, glycerol, fatty alcohols, triglycerides or mixtures thereof. See page 6,ln.15-40. Melrose teach adding the compounds at concentrations of 50-5000 mg/kg/day (page 5, lines 30-35). Melrose et al. teach that the antimicrobial composition is added at concentrations of 0.1% or 0.05% to drinking water of pigs after weaning and to treat colibacillosis. See examples 15 and 17.

Melrose '186 et al. teach that the composition further comprises one or more of methanol, acetone, tetra-hydrofuran, methyl ethyl ketone, benzoyl peroxide which exhibit a synergistic increase in antimicrobial activity. See examples 5-15 illustrating compositions comprising 1.5% antimicrobial polymer in 65% ethanol. See line 8 of pg.16. Melrose et al. teach the utility of poly(2-propenal, 2-propenoic acid) in humans, animals such as birds and mice having microbiological diseases of the gastrointestinal tract for example E. coli, and organisms such as Staphylococcus aureus, Helicobacter pylori, which cause gastrointestinal disease in animals. See page 8,ln.5-10. Melrose et al. teach the utility of a composition comprising poly(2-propenal, 2-propenoic acid) as an animal feed additive. See page 4, lines 15-20.

Melrose '186 do not teach the instant claimed method of heating the poly(2-propenal,2-propenoic acid) in the presence of polyethylene glycol.

Melrose '723 teach that the antimicrobial benefits of poly(2-propenal,2-propenoic acid) can be improved (page 4, lines 20-25). Melrose '723 further teaches in example 8 dissolving poly(2-propenal,2-propenoic acid) in polyethylene glycol 1000 at 70 degrees C , adding NaOH for 2 minutes heating for another 15 minutes (page 19, lines 5-15).

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Melrose '723 teach using the modified compound as a feed additive (page 4, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Melrose '186 by incorporating the modified poly(2-propenal,2-propenoic acid) taught by Melrose '723 because Melrose '723 teach the improved antimicrobial benefits of this compound over unmodified poly(2-propenal,2-propenoic acid) and its utility in an additive for animal feed.

Regarding the time limitation of heating for 1-1400 hours, this would just be a result effective variable and would influence the improvement of the antimicrobial action of the poly(2-propenal,2-propenoic acid). One of ordinary skill in the art would have been motivated to optimize this time limit to maximize the enhancement of antimicrobial activity.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 96/38186) in view of Melrose (WO 00/03723) in view of Harris et al. (US 2002/0127207).

Melrose '186 and Melrose '723 are relied upon as described in paragraph 5.

Melrose '186 and Melrose '723 do not teach rectal administration of the compounds.

Harris et al teach it is conventional to effectively treat livestock with antibacterial compounds by oral or rectal methods in animal feed or water (paragraph 0020) and are effective for treating e coli infections and diarrhea in pigs (paragraph 0007).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Melrose '186/'723 by incorporating the rectal administration techniques taught by Harris because Harris teach the functional equivalence of administering antimicrobials for treating disease orally and rectally as well as in animal feed and water. Substituting one known method of effectively administering a drug for another known method to arrive at the predictable result of treating disease is within ordinary skill in the art.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)272-5573. The examiner can normally be reached on Monday through Friday, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Amina Khan/

Examiner, Art Unit 1796

December 17, 2008

/DOUGLAS MC GINTY/

Primary Examiner, Art Unit 1796